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Nicole Powell-Dunford, Jose F. Quesada, Robert F. Malsby, Victoria Chou, Robert T. Gerhardt, Kirby Gross, and Stacy Shackelford

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USAF School of Aerospace Medicine
International Expeditionary Education & Training Dept
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14. ABSTRACT

Background: Between June – October 2012, 61 flight-medic-directed transfusions took place aboard U.S. Army Medical Evacuation (medevac) helicopters in Afghanistan. This represents the initial experience for pre-hospital blood product transfusion by U.S. Army flight medics.

Methods: We performed a retrospective review of clinical records, operating guidelines, after-action reviews, decision and information briefs, bimonthly medical conferences, and medevac-related medical records.

Results: A successful program was administered at 10 locations across Afghanistan. Adherence to protocol transfusion indications was 97%. There were 61 casualties who were transfused without any known instance of adverse reaction or local blood product wastage. Shock index (heart rate/systolic blood pressure) improved significantly en-route, with a median shock index of 1.6 (IQR 1.2 – 2.0) pre-transfusion and 1.1 (IQR1.0 – 1.5) post-transfusion (*P* , 0.0001). Blood resupply, training, and clinical procedures were standardized across each of the 10 areas of medevac operations.

Discussion: Potential risks of medical complications, reverse propaganda, adherence to protocol, and diversion and/or wastage of limited resources were important considerations in the development of the pilot program. Aviation-specific risk mitigation strategies were important to ensure mission success in terms of wastage prevention, standardized operations at multiple locations, and prevention of adverse clinical outcomes. Consideration of aviation risk mitigation strategies may help enable other helicopter emergency medical systems to develop remote pre-hospital transfusion capability. This pilot program provides preliminary evidence that blood product administration by medevac is safe.

15. SUBJECT TERMS
Blood, transfusion, medevac, pre-hospital, resuscitation

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Risk Management Analysis of Air Ambulance Blood Product Administration in Combat Operations

Nicole Powell-Dunford, Jose F. Quesada, Robert F. Malsby, Victoria Chou, Robert T. Gerhardt, Kirby R. Gross, and Stacy A. Shackelford

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Background: Between June–October 2012, 61 flight-medic-directed transfusions took place aboard U.S. Army Medical Evacuation (medevac) helicopters in Afghanistan. This represents the initial experience for pre-hospital blood product transfusion by U.S. Army flight medics. ***Methods:*** We performed a retrospective review of clinical records, operating guidelines, after-action reviews, decision and information briefs, bimonthly medical conferences, and medevac-related medical records. ***Results:*** A successful program was administered at 10 locations across Afghanistan. Adherence to protocol transfusion indications was 97%. There were 61 casualties who were transfused without any known instance of adverse reaction or local blood product wastage. Shock index (heart rate/systolic blood pressure) improved significantly en route, with a median shock index of 1.6 (IQR 1.2–2.0) pre-transfusion and 1.1 (IQR 1.0–1.5) post-transfusion ($P < 0.0001$). Blood resupply, training, and clinical procedures were standardized across each of the 10 areas of medevac operations. ***Discussion:*** Potential risks of medical complications, reverse propaganda, adherence to protocol, and diversion and/or wastage of limited resources were important considerations in the development of the pilot program. Aviation-specific risk mitigation strategies were important to ensure mission success in terms of wastage prevention, standardized operations at multiple locations, and prevention of adverse clinical outcomes. Consideration of aviation risk mitigation strategies may help enable other helicopter emergency medical systems to develop remote pre-hospital transfusion capability. This pilot program provides preliminary evidence that blood product administration by medevac is safe.

Keywords: blood, transfusion, medevac, pre-hospital, resuscitation.

THE U.S. ARMY MEDICAL evacuation (medevac) helicopter platform is the most recent of all military air ambulances to acquire blood product transfusion capability. Widely distributed across theater, the Army medevac is an ideal choice for rapid, forward pre-hospital blood product resuscitation. For patients undergoing medical evacuation, the largest portion of pre-hospital time will likely have been spent with the aircrew (11) and en route transfusion is especially justified in instances of long transport times (1). Damage control resuscitation, which favors early resuscitation with blood products over crystalloid fluids, is emerging as a standard practice in civilian and military trauma care (5). Resuscitation with crystalloid alone dilutes clotting factors. Resuscitation without increasing oxygen carrying capacity further undermines high-quality en route care.

Despite demonstrated feasibility and safety of existing pre-hospital blood product transfusion programs (2,7,22), a number of factors drove extra scrutiny of an Army medevac transfusion program. U.S. Army medevac has only recently evolved to require paramedic-level training for flight medics (12,16) and, at the time of implementation of the Army medevac transfusion program, large numbers of deployed Army flight medics remained certified only to the basic emergency medical technician level. In many locations, a single Army flight medic manages casualties independently, with only the assistance of a nonmedical crew chief. By comparison, the UK's Medical Emergency Response Team uses physician-directed in-flight transfusion (9) and U.S. Air Force Special Operations pararescue medics are highly trained paramedics and operate in teams of two (9). Unlike other military air ambulances in Afghanistan, the U.S. Army medevac helicopter is unarmed and marked with the red cross emblem, raising both political significance and risk of being shot down during a transfusion mission. And whereas the UK and Air Force Special Operations pararescue teams are based in close proximity to combat support hospitals with robust blood capability and subject matter expertise, many Army medevac companies are staged near less-equipped forward surgical hospitals with limited blood supplies. Recognizing a potentially higher risk for medical complications and wastage of critical resources in the forward Army medevac companies, a deliberate approach was undertaken in the development of the transfusion training and protocol fielded by the 25th Combat Aviation Brigade. Successful approval and implementation were largely due

From the U.S. Army Health Clinic, Schofield Barracks, Wahiawa, HI; the 440th Blood Support Detachment, Fort Sam Houston, TX; Womack Army Medical Center, Fort Bragg, NC; the USAF Center for Sustainment of Trauma and Readiness Skills, Baltimore, MD; the U.S. Army Institute of Surgical Research, Department of Emergency Medicine, San Antonio Military Medical Center, Fort Sam Houston, TX; and the Joint Trauma System, U.S. Army Institute of Surgical Research, Department of Emergency Medicine, San Antonio Military Medical Center, Fort Sam Houston, TX.

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Address correspondence and reprint requests to: Nicole Powell-Dunford, 1345 Parks Drive, Honolulu, HI 96819; nicole.c.powell-dunford.mil@mail.mil or nikkipd@gmail.com.

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to the application of aviation risk analysis and mitigation strategies. The deliberate application of aviation-based practices, such as the use of a checklist and well-established communication procedures, has already demonstrated superior health care delivery in the civilian sector (6,20). The following problem-oriented discussion enumerates the specific risks of en route transfusion and how aviation risk management strategies were undertaken.

METHODS

Clinical operating guidelines, after-action reviews, bimonthly medical conference proceedings, and decision and information briefs were retrospectively reviewed to identify specific aviation risk mitigation strategies adopted by the medevac blood product program. Incidence of blood wastage and adverse outcomes related to transfusion were established through review of medevac-related medical records, after-action reviews, and bimonthly medical conferences. All medevac and available in-hospital patient records were reviewed to identify patient-specific characteristics and compliance with transfusion protocols.

Data analysis was performed using STATA (Stata Statistical Software: Release 12; College Station, TX: StataCorp; 2011). Because the data were not normally distributed, medians with interquartile ranges were used to describe age and vital signs. Additional demographic details (e.g., gender and nationality) were also reported. A two-tailed Wilcoxon signed-rank test was performed to compare the difference between vital signs and the shock index reported pre- and post-transfusion for casualties with at least two sets of vital signs recorded during medevac.

RESULTS

Between June and October 2012, 61 casualties were transfused. Characteristics of medevac transfusion recipients are displayed in **Table I**. Of the 61 patients, 59 (97%) met predefined transfusion indications [severe traumatic injury with heart rate (HR) > 120, systolic blood pressure (SBP) < 90, or any proximal limb amputation]. In total, 57 units of packed red blood cells (PRBC) and 14 units of thawed plasma were administered to 61 casualties. Transfusion was administered by intravenous catheter in 37 (61%) and by intraosseous needle in 23 (38%). There were 46 (75%) casualties who required placement of one or more tourniquets. The median PRBC received by all casualties was 10 units (range 1-29) PRBC in the first 24 h. Short-term (24-h) survival was known in only 49% of the blood transfusion recipients and was not available for casualties delivered to Afghan local hospitals. Of those patients admitted to U.S. surgical hospitals, 23 survived and 8 died, including all 4 who required cardiopulmonary resuscitation en route.

Comparison of vital signs pre- and post-transfusion is displayed in **Table II**. Shock index (HR/SBP) improved significantly en route, with a median shock index of 1.6 (IQR 1.2–2.0) pre-transfusion and 1.1 (IQR 1.0–1.5) post-transfusion ($P < 0.0001$). There were no instances of regional blood wastage or failure to transfuse a casualty meeting pre-designated transfusion indications. There were no identified transfusion reactions.

TABLE I. CHARACTERISTICS OF PRE-HOSPITAL BLOOD TRANSFUSION RECIPIENTS, *N* = 61.

Age* (yr) [median (IQR)]	24 (20–28)
Gender [*N* (%)]	
Male	60 (98)
Patient category [*N* (%)]	
Coalition Military	15 (25)
Afghan	46 (75)
Mechanism of Injury [*N* (%)]	
Explosion	45 (74)
Gunshot wound	16 (26)
Indication(s) for transfusion [*N* (%)]	
HR > 120	50 (82)
SBP < 90	32 (52)
Proximal amputation	23 (38)
Prehospital transfusion(s) [*N* (%)]	
PRBC 1 unit	44 (72)
PRBC 2 units	3 (5)
Plasma 1 unit	7 (11)
Plasma + PRBC	7 (11)
Additional 24 h blood products {median (IQR) [Range]}	
PRBC	10 (8–14)[1–28]
Plasma	9 (6–13)[0–30]
Platelets	1 (0–2)[0–12]
Cryoprecipitate	10 (0–10)[0–30]
Pretransfusion vitals [median (IQR)]	
SBP**	86 (70–104)
DBP	52 (40–66)
HR†	133 (125–141)
RR††	18 (14–22)
Post-transfusion vitals [median (IQR)]	
SBP**	108 (85–127)
DBP	60 (47–71)
HR†	125 (110–138)
RR††	16 (12–18)
Venous access type‡ [*N* (%)]	
IV	37 (61)
IO	23 (38)
Unknown	1 (2)
Labs on arrival	
Base deficit	9 (6–14)
Hemoglobin	12 (11–14)
INR	1.2 (1.1–1.4)
Prehospital interventions [*N* (%)]	
Tourniquet	46 (75)
Advanced airway	7 (11)
Chest decompression	4 (7)
CPR	4 (7)
24-h survival‡‡ [*N* (%)]	
Yes	23 (38)
No	8 (13)

IQR = Interquartile range, *N* = number, HR = heart rate, SBP = systolic blood pressure, DBP = diastolic blood pressure, PRBC = packed red blood cells, RR = respiratory rate, IV = intravenous, IO = intraosseous, INR = international normalized ratio, CPR = cardiopulmonary resuscitation.
* Age not reported for *N* = 6.
** SBP/DBP not reported for *N* = 3 (pre-transfusion) and *N* = 23 (post-transfusion).
† HR not reported for *N* = 4 (pre-transfusion) and *N* = 22 (post-transfusion).
†† RR not reported for *N* = 12 (pre-transfusion) and *N* = 31 (post-transfusion).
‡ Venous access not reported for *N* = 1
‡‡ 24-h survival not reported for *N* = 31. (In-hospital data not available for Afghan patients delivered to Afghan hospitals.)

TABLE II. COMPARISON OF VITAL STATUS PRE- AND POST-TRANSFUSION, *N* = 38

Vital Sign or Marker	Definition	Pre-Transfusion Median (IQR)	Post-Transfusion Median (IQR)	*P*-Value*
SBP†	Systolic BP	86 (70–104)	108 (85–127)	0.001
HR††	Heart rate	133 (125–141)	125 (110–138)	0.000
Shock Index (SI)‡	HR/SBP	1.6 (1.2–2.0)	1.1 (1.0–1.5)	0.000
Modified Shock Index (MSI)	HR/mean BP‡‡	2.2 (1.7–2.6)	1.7 (1.3–2.1)	0.000

* Based on results of Wilcoxon signed-rank test to compare matched samples.
† SBP/DBP not reported for *N* = 3 (pre-transfusion) and *N* = 23 (post-transfusion).
†† HR not reported for *N* = 4 (pre-transfusion) and *N* = 22 (post-transfusion).
‡ SI cannot be calculated for *N* = 4 (pre-transfusion) and *N* = 22 (post-transfusion).
‡‡ Mean BP is defined as (DBP × 2)/3.

DISCUSSION

Focus areas for risk mitigation undertaken by the medevac blood product transfusion program included medical risk, adherence to transfusion protocol, risk for reverse propaganda, and risk for blood product wastage at local and regional levels. A number of aviation risk mitigation strategies, including risk analysis, standardization, and technical inspection, were employed. Each risk and all corresponding aviation risk mitigation strategies will be fully described. The safety of transfusion was paramount in the Army medevac transfusion program, particularly with respect to patient medical risks. In a recent review of a civilian rural aeromedical transport experience, transfusions were infrequent but potentially life-saving. Strict compliance with an established protocol resulted in appropriate and effective decisions, with transfusion proving to be a safe in-flight procedure (7). A similar attention to transfusion protocol was essential to safe transfusion in our experience.

Mild transfusion reactions such as low grade fever and pruritus may affect 1–3% of patients receiving a transfusion (17), with a greater incidence in patients with a history of prior transfusions or who undergo massive transfusion. Serious reactions include hemolytic transfusion reactions, transfusion-associated sepsis, anaphylaxis, and transfusion-related acute lung injury, which affect 1:76,000; 1:500,00; 1:50,000; and between 1:1200–1:190,000 transfusions, respectively (10,17). For the Army medevac transfusion program, blood products were carefully chosen to address logistical constraints while minimizing the risk of transfusion reaction. Group O negative or O positive PRBC were approved for universal use as well as group AB and group A plasma. O negative red blood cells were preferred rather than mandated in female casualties. To ensure that the correct blood and plasma types were loaded into the blood product storage container ("Golden Hour Container"), laboratory technicians conducted a two-way check prior to container handoff to the flight medics. An in-flight cross check was also undertaken between the flight medic and crew chief prior to the spiking of any blood product unit. The risk of an acute transfusion reaction is very low, but necessitates training and equipment to manage appropriate treatment. Training must involve rapid recognition and management of transfusion reactions, especially in air ambulance systems performing evacuation without a physician or nurse. A medical checklist for the management of transfusion reactions, including acute hemolytic reaction and anaphylactic shock, was available inside the blood storage container and flight medics were trained on this emergency procedure.

One study has shown an association between in-flight transfusion and hypothermia when intravenous fluid warming measures are not undertaken (21). The administration of cold plasma and/or PRBC can impair optimum oxygen delivery, generate cardiac arrhythmias, and contribute to hypothermia. For in-flight transfusion, the U.S. Army medevac employs an air-worthy warming device (En Flow, Enginivity LLC, Lexington, MA; NSN 6515-01-553-0107 or Thermal Angel, Estill Medical Technologies, Dallas, TX; NSN 6515-01-500-3521) to help prevent transfusion-related hypothermia. Deployed Army flight medic training also incorporated standard hypothermia prevention measures, including removal of wet clothing and use of chemically active warming blankets for all casualties. Even in a desert environment with temperatures in excess of 50°C, hypothermia remains a concern for volume-depleted casualties undergoing air evacuation.

The use of expired blood products or blood products that have been compromised by unacceptable temperature excursions is of particular concern in the austere desert environment. Redundancy in temperature regulation of the blood products was developed in a number of ways. Although the Golden Hour Container is validated to maintain acceptable blood product temperatures of 0 to 10°C for up to 72 h, the U.S. Army medevac protocol mandated a handoff every 24 h as well as at the time of casualty delivery. Fight medics were furthermore trained to confirm the operability of the Golden Hour Container before use by gentle shaking, which will cause sloshing if not properly conditioned to the correct temperature. As a final and definitive measure, a temperature indicator was affixed to each unit of blood product that incurred an irreversible color change for any excursion outside the required temperature. The pre-transfusion checklist included inspection of the temperature indicator. Pre-implementation training was also conducted in the dark to ensure the ability of the flight medic to recognize the color change during nighttime operations.

The risk of transfusion-related human immunodeficiency virus and hepatitis C are estimated to be less than 1 in a million, with risk for hepatitis B 1:764,000; the time window from inoculation to a positive serum test for these infectious diseases ranges from 3 d to 28 d (18). U.S. Food and Drug Administration approved, fully screened blood products were exclusively used in the program due to theoretical prion disease risk and variable blood product screening techniques in coalition and host nation blood banks. Donor information number of each unit was populated onto the transfusion paperwork prior to loading within the storage container and was transferred with any transfused casualty. The donor information number was additionally cross checked between the flight medic and crew chief prior to spiking of the unit. Robust paper and electronic documentation of the donor information number was made through entry of the number into the transfusion record itself, a separate written note into the patient's medical record, as well as an electronic entry into the Army's electronic health record for U.S. Department of Defense casualties. Ongoing process improvement monitoring include tracking of the donor information number as well as a comprehensive medevac transfusion log regardless of casualty service or nationality. As part of the U.S. Army medevac program, any of the units that were initiated but not completely transfused remained with the patient to ensure availability for documentation.

The decision to initiate transfusion is a challenge faced by flight medics and medical directors. The transfusion procedure is guided by a protocol that is trained and implemented by flight medics. No definitive physiological indications for transfusion have been identified in various retrospective studies (3,14,15) and clinicians rely to a great extent on judgment for early initiation of transfusion in acutely hemorrhaging trauma patients. The development of the U.S. Army medevac transfusion protocol has been previously described (13); however, in brief, it is based on damage control resuscitation guidelines (8) with indications for transfusion specifically defined as serious injuries with HR $>$ 120, SBP $<$ 90, or any proximal limb amputation. In the 61 casualties who received blood product transfusion, 59 casualties (97%) clearly met the predefined criteria. One casualty early in the program received a transfusion for a decrease in mental status with normal vital signs, which was interpreted by the medic to be a potential indicator of hemorrhagic shock. This was addressed with further training emphasis and did not recur. Another casualty had significant soft tissue injuries of two extremities with normal vital signs and went on to receive 8 units of PRBC in the first 24 h. Notably, flight medics were required to make a clinical judgment that serious traumatic injury was present before initiating transfusion for the vital sign indicators. We established that the medics were able to make this determination and, with the exception noted above, over-transfusion did not occur in cases of less serious injury.

Aviation-specific tasks are taught by certified instructors who ensure safe and standardized operating procedures. A checklist is used to ensure all steps are followed in sequence. Standardization of training and the use of checklists ensure seamless flight operations across multiple operating areas. Likewise, preflight procedures such as Golden Hour Container inspection and exchange, transfusion initiation, and management of transfusion reactions was taught in conjunction with specific checklists. The program of instruction for laboratory technician and flight medic training was also standardized to ensure identical handoff and safety checks, regardless of service affiliation or component (Reserve, National Guard, or active duty) of the medical personnel or supporting field medical facility. The lead trainers, or standardization instructors, were critical care nurses with experience in blood product transfusion. Further review of the training program was conducted by surgeons and emergency room physicians at institutional levels. Instructors provided realistic day and nighttime training and conducted practical as well as written examination using standardized measurement tools. Critical tasks required for successful flight medic certification included adherence to universal precautions, establishment of maximal hemorrhage control prior to initiation of a transfusion, use of a fluid warmer for transfusion, recognition of a transfusion reaction, and confirmation of the donor information number. Prior to implementation of the program, the entire flight crew participated in a validation exercise, demonstrating effective handoff and return flight communication procedures for resupply.

Even a single adverse outcome can generate public hostility against an air ambulance operation in a deployed setting. Infected or tainted plasma and red blood cells have theoretical application as biological warfare agents. Historically, covert immunization programs used to secure genetic material in Pakistan bred mistrust in humanitarian aid throughout the region. Additional reverse propaganda themes surrounding U.S. humanitarian aid included allegations that the U.S. Government administered agents known to transmit human immunodeficiency virus or cause sterility in a civilian populace (19). In the U.S. Army medevac transfusion program, the possibility of adverse propaganda was mitigated by scrupulous adherence to the transfusion protocol and by the early, pre-implementation involvement of the host nation blood bank and Afghan medical personnel to ensure full transparency of the program.

Legitimate concerns exist regarding the use of blood products in any helicopter emergency medical system. A retrospective analysis of urgent medical evacuations in the Iraq war proposed that only 15% of urgent transports would be candidates for notional pre-hospital blood product administration (4), and short flight times predominate in evacuations in Afghanistan since 2010 (9). Thawed plasma and packed red blood cells must be used by an air ambulance team within a specific time frame prior to becoming compromised for safe use and must be administered within hours of unit spiking to prevent bacterial infection. Universal donor blood products, particularly AB positive plasma, are in short supply.

Platelets must be constantly agitated and maintained at room temperature, effectively excluding them from any pre-hospital use. However, a recent study examining pre-hospital blood product use substantiated that remote transfusion programs can deliver life-saving therapy without waste. In a series of 2500 units of plasma transported for pre-hospital use, 100% of unused plasma was subsequently transfused (22). A critical element in waste mitigation is the timely return of non-used blood products to surgical hospitals. Rotation of blood products between lab and flight crews demanded rigorous adherence to a daily exchange, as well as a rapid resupply capability on patient transfer. In order to effect rapid resupply, a radio transmission was developed in which flight crews transmitted a code word to receiving surgical facilities at the time of initiating in-flight transfusion.

Quality assurance in aviation is undertaken through technical inspection and resource management inspection. Defects are identified and remediated at the flight line so that they do not become a hazard in flight. Resource management inspection ensures that systems and processes are undertaken in a standardized fashion. The U.S. Army medevac transfusion program was likewise tied to a comprehensive process improvement program coordinated by the Joint Theater Trauma System. Prior to theater-wide approval of the medevac blood transfusion protocol, each of the first 15 missions were subjected to a complete after-action review (AAR) by teleconference between the flight crews, trainers, senior aeromedical officers, theater blood support, and trauma experts (13). The AAR's scope involved a comprehensive assessment of each mission and the program as a whole, including blood product exchange procedures, initial trauma management procedures, indications for transfusion, technical implementation of the transfusion procedure, documentation procedures, and the transfused patient handoff procedure. During the review period, the transfusion protocol was modified to address all identified concerns. AARs reinforced the need for high-quality day and night training along with ongoing weekly reviews. Additionally, AARs led to a modification of the indications for transfusion as well as a strong recommendation that two medics were needed for urgent medevac missions with the possibility of blood product transfusion.

Theater-wide data collection related to helicopter administered blood products is ongoing. Although the impact of pre-hospital blood product transfusion on end organ perfusion and casualty survival is not yet fully established, safety and feasibility have been demonstrated. Aviation-based risk mitigation strategies have positively impacted the approval and successful implementation of a new Army medevac program. In particular, the aviation culture places a premium on safety and standardization, the development of robust and redundant communications for high-risk operations, the use of checklists and cross checks, as well as technical and resource management surveys for process improvement. Air ambulance systems seeking to implement pre-hospital blood product programs may benefit from adoption of aviation risk management strategies. This review provides preliminary evidence that blood product administration by medevac is safe. This is a key first step to move damage control resuscitation closer to the point of injury for conventional forces.

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Authors and affiliations: Nicole Powell-Dunford, M.D., M.P.H., FAAFP, U.S. Army Health Clinic-Schofield Barracks, Wahiawa, HI; Jose F. Quesada, M.S., M.D., 440th Blood Support Detachment, and Robert Gerhardt, M.D., M.P.H., FACEP, U.S. Army Medical Department Center and School, Fort Sam Houston, TX; Robert F. Malsby III, D.O., FAAFP, Department of Obstetrics & Gynecology, Womack Army Medical Center, Fort Bragg, NC; Kirby Gross, M.D., FACS, U.S. CENTCOM Joint Theatre Trauma Systems Director, MacDill AFB, FL; Victoria Chou, Ph.D., USAF Center for Sustainment of Trauma and Readiness Skills, University of Maryland Medical Center, R. Adams Cowley Shock Trauma Center, Baltimore, MD; and Stacy Schackelford, B.S., M.D., FACS, U.S. Air Force Center for Sustainment of Trauma and Readiness Skills, Baltimore, MD.

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